Advancing Transfusion and
Cellular Therapies Worldwide

STATEMENT OF THE AABB
BEFORE THE
SUBCOMMMITEE ON AFRICA, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL OPERATIONS

MAKING SAFE BLOOD AVAILABLE IN AFRICA
June 27, 2006

Good morning Chairman Smith and members of the Subcommittee. My name is Karen Shoos Lipton and I am Chief Executive Officer of AABB. On behalf of AABB's members we thank you for the opportunity to testify on the important role of the Presidents' Emergency Plan for AIDS Relief (PEPFAR) in improving blood safety in Sub-Sahara Africa and the Caribbean.

AABB is a professional society at its core, representing approximately 8,000 individual professionals in the fields of blood banking, transfusion medicine and cellular therapies and 1,800 institutions, including blood centers, hospital-based blood banks and transfusion services. Approximately 20 percent of our members are located outside of the United States in 80 countries around the world.

For over 50 years, AABB has set voluntary standards for and accredited blood centers and transfusion services. In addition, we promote quality care for patients through our standard-setting and accreditation of cord blood and hematopoietic stem cell collection and storage facilities, immunohematology reference laboratories, and relationship testing laboratories. In fact, AABB, was the original developer and author of quality system essentials, which are now used by a number of organizations as the basis for their standards and accreditation programs.

Globally, in addition to our role as a blood safety "Technical Assistance" provider under the PEPFAR program, AABB has formal and informal liaison relationships with many organizations around the world and has been involved in numerous blood safety projects. For example, we are a founding and active member in the World Health Organization's Global Collaboration for Blood Safety. Jointly with the Pan American Health Organization, AABB assisted in the development of regional standards and implementation guidance for blood banks and transfusion services in the Caribbean region and delivered initial training on those standards to representatives from 22 countries. In 2004, we developed and delivered training for the Canadian government's blood bank regulatory inspectors. Through our voluntary accreditation program we perform assessments and accredit 49 blood collection and transfusion facilities in 16 countries.

More recently we signed two memoranda of understanding with the Chinese Society of Blood Transfusion and Shanghai Blood Center to develop professional education and technical programs in China and were selected as a subcontracting organization for a United States Agency for International Development (USAID) grant to improve blood safety in the country of Moldova.

AABB's Experience as a Technical Assistance Provider in Africa

Under the President's Emergency Plan for AIDS Relief, AABB is the Technical Assistance provider to six of the 14 focus countries, Guyana, Kenya, Mozambique, Rwanda, South Africa and Tanzania.

As a Technical Assistance provider, AABB's role is to work with each country's Ministry of Health and National Blood Transfusion Service (NBTS) to strengthen the blood supply and address safety systems. The seven key areas identified by the Office of the Global AIDS Coordinator (OGAC) and the Centers for Disease Control and Prevention (CDC) as meriting attention include:

1. Infrastructure
2. Blood Collection
3. Blood Testing and Processing
4. Transfusion and Blood Utilization
5. Training
6. Monitoring and Evaluation
7. Sustainability

AABB's approach is, first, to conduct a complete assessment of the existing situation in each country. We perform a detailed "vertical" assessment of the country's infrastructures that impact blood transfusion, including:

- enabling legislation;
- regulatory systems;
- government policies;
- NBTS policies and organizational structure;
- financial support for the blood program;
- educational systems; and
- infrastructure (e.g., roads, electricity).

Concurrently, we assess horizontally the NBTS management, operational systems, and infrastructure, including:

- staff training;
- donor recruitment;
- donor evaluation and screening;
- blood testing and processing;
- storage and distribution; and
- transfusion practices and blood utilization.

Once the assessment is completed, it is shared with the Ministry of Health and the NBTS in each country and, together, we develop a customized five-year work plan targeted at each area requiring improvement. From our decades of experience in the United States, and more recently in other regions of the world, we believe a key to advancing transfusion medicine and blood safety is assisting each country in establishing national standards that are based on universally accepted quality principles, but tailored to the individual public health needs and resources of each country. Such standards allow the countries to implement their own quality systems that can be sustainable into the future, even with the inevitable transition of personnel in the country and after U.S. partners in this program have departed.

At this time, AABB is actively engaged in each of its six countries, working under organized and coordinated work plans for each. Each country, of course, is unique, but there are common problems that create significant challenges.

To provide some perspective about the complicating factors that need to be addressed, we would like to provide you with a few real examples from our experiences:

- *Standardized Testing and Collections:* As a general goal, AABB and others involved with PEPFAR's blood safety program are all working toward standardizing the collection and testing of blood and, in general, reducing the number of locations where these activities are performed. We have all witnessed, first-hand, some of the deplorable conditions - non-functioning or non-existent equipment, no standard operating procedures and barely trained staff - that exist in some of the blood collection and testing sites. In some countries, centralization of some of the activities, particularly of testing, can serve to increase the quality of practice. As a practical matter, however, this is not a solution that works in every country. The very real problems of lack of roads and transportation, including in some places, whole areas of the country that are inaccessible during the rainy season, and the difficulties of maintaining an effective cold chain for this perishable material, require that additional sites be established and maintained, if we are to ensure the availability of blood for all patients in need. The very basic challenge of providing this service in areas that have unreliable electricity and water is daunting.

- *Rapidly Expanded Funding:* Often, even the simple process of accepting and disbursing funds becomes a roadblock to success. As an example, in one of our countries, it took nearly 10 months to open a bank account to receive PEPFAR funds and establish the requisite authority to access the funds. Even more common is the concentration of signature authority for the disbursement of funds in one person who must approve every purchase, from equipment, to reagents, to pencils. Further complicating the situation in most countries is that the NBTS is generally required to utilize the tender and procurement system that typically resides in the Ministry of Finance, and which is often cumbersome and based solely on a principle of lowest bid, without regard to technical compatibility or quality.

- *Limited Senior Staff:* In most countries there is only one or, at best, a few senior staff with the education and experience necessary to manage the NBTS operations. And, many of the individuals in these countries hold several positions, including Ministry of Health or public health laboratory responsibilities. Their schedules are further complicated by the sheer number of foreign government and non-governmental organizations (NGOs) operating in many of these countries. It is not uncommon for these individuals to spend entire days and weeks just attending meetings with these funding organizations, leaving little, if any, time to actually implement the changes or manage the day-to-day activity. This very real problem limits the capacity of the country to effectively deal with funding opportunities.

- *Sustainability:* The ability to sustain the improvements in blood safety into the future beyond the PEPFAR funding period is dependent on recognizing many inter-related factors, some of which are outside of the control of the NBTS. Several examples include:

    1. Need for sustainable financial systems for blood programs. Most countries have a limited understanding of the costs required to maintain a safe and adequate blood supply. One solution may be to establish a per-unit cost recovery system whereby the per unit charges can be passed on to the patient, insurance and/or into the hospital budget on a rationale usage. This solution, however, will be extremely difficult to implement and may have the effect of undermining efforts to create a voluntary blood supply as donors question why patients must pay for something that is given for free.
    2. Need for educational and training systems that properly prepare individuals for jobs and careers in the blood bank, transfusion medicine and/or laboratory fields. In most NBTS's, the collection and laboratory staff are almost completely trained in an "on the job training" format, with minimal, if any formal education in the medical or laboratory field. Physicians often have had no, or very limited, instruction in transfusion medicine and proper blood utilization and administration. Even in those countries where training programs exist, the technical schools are often challenged by a lack of textbooks, materials and equipment required to teach the necessary skills.
    3. Need for total systems and strategic approach. On a day-to-day basis, the NBTS's are continually operating in a crisis-management mode, requiring them to focus their attention narrowly on solving each isolated, immediate problem, rather than looking at the overall systems and putting in place a more permanent system-wide solution. For example, if a facility runs out of test kits, it will most often "beg, borrow and steal" from another lab or facility, rather than focusing on improving the inventory and procurement process to avoid repeating the situation the following month.

AABB Supports Gradual Expansion of the Blood Safety Program

PEPFAR funding for improvements to the safety and supply of blood for transfusion has saved the lives of countless people, mostly children and women of child bearing age, in the 14 focus countries. Congress should also be aware that the improvements to blood safety and availability made under the name of AIDS/HIV prevention have the added benefit of reducing the risk of many other transfusion-transmitted diseases, most notably hepatitis B, and in reducing the biggest risk of blood transfusion—the lack of blood when it is needed. Additionally, improvements to compatibility testing and transfusion practices are providing significant improvements to the clinical outcomes and reductions in the risk of transfusion-related complications, including the potential for death, that far exceed the benefits of reducing the risk of AIDS/HIV alone. Finally, it is important to recognize that blood is a critical health care infrastructure. Without improvements to the safety and availability of blood, further improvements to health care, including treatment for cancer, malaria and surgeries, will not be possible.

AABB supports the expansion of the federal government's efforts to improve the safety and supply of blood in Africa but we need to also emphasize the need for a well organized and deliberately phased approach to such expansion that recognizes the real limitations in the infrastructure and healthcare systems of these countries.

Specifically, we would like to make three key points. **First, in our experience, each country's ability to make improvements is based on several limiting factors, most notably the lack of properly educated/trained human resources; limited existing healthcare delivery systems; and basic, often insufficient, infrastructures.** Funding massive improvements to the NBTS without recognizing each country's capacity properly to utilize the funds, appropriately to utilize blood and blood components, or to build supporting infrastructure, will result in a failed effort in the long term. PEPFAR Technical Assistance providers and NBTS's work plans need to take a "complete systems" approach, and not an "emergency" or crisis management approach to addressing all of these substantial barriers. Moreover, the work plans need to address the blood supply needs of the entire country, which often requires time-consuming and deliberate efforts.

Second, the number of technical experts in the field of blood banking and transfusion medicine available globally to provide the necessary assistance is limited. There are a limited number of individuals from high human index development countries who are available to spend the time necessary to provide real assistance. Attempts to attract qualified individuals from other African countries with better blood systems only serves to de-stabilize those blood programs. Within the focus countries themselves, there are few qualified professionals who can extend that knowledge to the next generation of blood providers. If PEPFAR's blood safety program is expanded to cover additional African countries, careful consideration must be given to assuring that technical experts do not "desert" one country still in need in an effort to help another. Systems must be put in place to begin training sufficient numbers of blood banking and transfusion medicine providers.

Third, in order to fully benefit African patients, attention must be given to improving transfusion medicine "vein to vein" – from the collection of blood from volunteer donors, to the safe testing and processing of the blood components, to the act of transfusing these products into patients. It is not enough that we improve infectious disease testing of blood; we must also work to ensure that the units are appropriately stored until the time of transfusion and that each patient gets the right unit of blood. The wrong unit to the wrong patient or hemolysis of a unit of blood that is not stored at an appropriate temperature can kill as effectively as any disease. Blood transfusions are a significant therapy in the treatment of complications relating to childbirth, pediatric anemia related to malaria, and victims of trauma. Absent the necessary improvements in all aspects of blood - donor recruitment, blood collection and processing, testing and blood administration - we will not achieve our goal of making blood safe and available for these patients in need.

AABB urges this Committee and Congress to support the development of a well organized plan for the expansion of the blood safety program in three ways:

1. **Incrementally expand funding to technical assistance providers and the 14 PEPFAR focus countries based on realistic estimates of human resource capacity and the countries' ability to absorb the increased funding effectively.**

2. **Add non-focus countries into an organized blood safety improvement program, again in an incremental, organized and sustainable manner.**

3. **In light of the current status of blood safety programs and the substantial work to be done, extend PEPFAR blood safety funding beyond the current March 2010 deadline for development of a sustainable blood safety program.**

AABB would welcome the opportunity to work with Congress, OGAC, CDC and other interested parties to develop a comprehensive plan for blood safety in the PEPFAR focus and non-focus countries. Thank you for the opportunity to express our opinions and share our experiences in the development and implementation of blood safety programs globally.